July 24, 2001

FACT SHEET

AMENDMENTS TO FINAL AIR TOXICS RULE FOR PHARMACEUTICAL PRODUCTION

TODAY'S ACTION

- The Environmental Protection Agency (EPA) is promulgating several amendments to its rule reducing toxic air pollutant emission from pharmaceutical production. These amendments correct referencing errors, add test methods for analyzing wastewater, change the listing of triethylamine from partially soluble to soluble, and add planned routine maintenance provisions for centralized combustion control devices.

- Toxic air pollutants, orair toxics, are those pollutants known, or suspected, to cause cancer and other serious health problems. Air toxics are emitted during the pharmaceutical manufacturing process, which consists mainly of chemical operations used to produce drugs and medication.

- Today's amendments will not change the health and environmental effects of the rule, and they will not change the requirement that new and existing major sources control air toxics emissions.

WHAT THE AMENDMENTS WOULD DO

- These amendments will allow pharmaceutical production facilities to routinely use additional testing methods to ensure compliance with the September 1998 rule. The two new methods can be used to measure certain compounds (e.g., methanol, acetonitrile, and n-hexane) that cannot be measured using the other methods accepted by EPA. These methods have already been added to the Pharmaceutical Effluent Guidelines and Standards and will provide convenience to many companies when they are adopted.

- EPA proposed these various amendments as a response to important issues that were raised by the industry at time of promulgation of the rule.

- EPA will list triethylamine in wastewater as a soluble air toxic so that it can be controlled using biological treatment. This change addresses the special dissociation property of triethylamine, and makes the treatment options for triethlyamine consistent with other EPA rules controlling air emissions of this compound.

- During the planned routine maintenance period for a centralized combustion control device (a combustion unit that controls air pollution from vents for several processes), EPA will require pharmaceutical manufacturers to maintain a level of control that is equivalent to the minimum control level allowed for a source of toxic air pollutants.

BACKGROUND

- EPA issued its final air toxics rule for pharmaceutical production in September 1998. That rule required the application of maximum achievable control technology (MACT), for approximately 100 facilities manufacturing pharmaceutical products.

- Pharmaceuticals manufacturing operations covered by the rule include chemical synthesis, formulation, fermentation and extraction processes. The major air toxics to be controlled include methylene chloride, methanol, toluene, and hydrogen chloride. Methylene chloride is considered to be a probable human carcinogen. The other pollutants can cause serious health problems other than cancer in humans.

- The final rule is expected to reduce air toxics emissions by 24,000 tons per year -- a 65 percent reduction from 1998 levels. It also reduces volatile organic compound (VOC) emissions, which contribute to the formation of ground-level ozone (smog).

FOR MORE INFORMATION

- For further information about the proposal, contact Randy McDonald of EPA's Office of Air Quality Planning and Standards at (919) 541-5402.

- EPA's Office of Air and Radiation's home page on the Internet contains a wide range of information on the air toxics program, as well as many other air pollution programs and issues. The Office of Air and Radiation's home page address is: http://www.epa.gov/oar/.